

REMARKS

The undersigned would like to begin by thanking the Examiner for his time and suggestions during the telephonic interview on January 30, 2004. The amendments and remarks presented herein include matters discussed during the interview. As stated in the Examiner's Interview received by facsimile on February 3, 2004, claims 1, 14 and 24 were deemed fully enabled by the Specification and the Section 112, first paragraph, rejection of claims 1, 14 and 24 was withdrawn. In addition, the amendment to claim 1 proposed by the applicant and reflected in the present Amendment and Remarks was discussed. Finally, the Examiner stated that an inadvertent error was made in excluding claim 69 in the Section 103(a) rejection based on Gabetta et al.

In the final Office Action, Paper No. 8, all pending claims 1-9, 11, 14-28, 61-62, 65-66, and 69-72 were rejected. In response, claims 1, 65, 69, and 71-72 have been amended herein. Support for the claim amendments can be found in the Specification at paragraph [0041], as discussed below in detail. As a result of this amendment, claims 1-9, 11, 14-28, 61-62, 65-66 and 69-72 remain pending for the Examiner's consideration. None of the amendments set forth herein constitute the addition of new matter. Reconsideration of the application as amended is respectfully requested. Withdrawal of the objections to the specification, objections to claims 20 and 44, the rejection of claims 26, 29, 48, 54, and 58 under Section 112, second paragraph, and the Section 102(b) rejections as stated on page 2 of the final Office Action is acknowledged.

A. Rejections under 35 U.S.C. § 112, first paragraph, addressed

The rejection of claims 1, 14 and 24 under 35 U.S.C. § 112, first paragraph, was maintained in the final Office Action. However, during the telephonic interview of January 30, 2004, the Examiner stated that upon further consideration, claims 1, 14 and 24 were indeed fully enabled and hence this rejection was withdrawn.

B. Rejections under 35 U.S.C. § 103(a) addressed

1. The rejection of claims 1-9, 11, and 14-28 under 35 U.S.C. §103(a) as being unpatentable over Gabetta in view of GB Patent No. 1,235,379 to S.O.R.I. was maintained for reasons of record in paper No. 5. This rejection is respectfully traversed. It is asserted that the cited references do not expressly or inherently teach or suggest all the elements as set forth in claims 1-9, 11, and 14-28 for the reasons presented below. Hence, a *prima facie* case of obviousness under 103(a) cannot be maintained.

The Examiner relies on Gabatta in part for teaching the use of bisulfite ions in isolating anthocyanins. In the Interview Summary received by facsimile on February 3, 2004, the Examiner agreed with the suggestion that adding the limitation of excluding the use of bisulfite ions to claim 1 would distinguish the present invention from the prior art. Accordingly, claim 1 has been amended herein to further clarify the differences between the method of the present invention and Gabetta by reciting that the method includes preparing a crude extract of a plant material by a method that excludes the addition of bisulfite ions. Support for this amendment can be found in the Specification at paragraph [0041]. Therefore, the Examiner's rejection based on the fact that "Gabetta teaches adding a source of bisulfite ions" is moot in light of this amendment, since Gabetta requires the addition of bisulfite ions, whereas the presently amended claims specifically exclude the addition of bisulfite ions. On this basis alone the rejection should be withdrawn.

In addition, the Examiner relied on the S.O.R.I reference primarily for teaching the use of an anion exchange resin to enhance the purification of the isolated anthocyanin, and further the Examiner asserts that anion exchange resins belong to the same class of resins as the brominated polystyrene resin (see page 5, paragraph 4 of the final Office Action). However, the Examiner's use of the S.O.R.I. reference is based on an erroneous assumption. Polystyrene resins, including brominated polystyrene resins, are not anion exchange resins, but rather are nonpolar resins. Thus, since the S.O.R.I reference does not teach or even suggest the use of a nonpolar resin, let alone a brominated polystyrene resin, this reference is irrelevant to the patentability of the present invention. As stated in the Amendment filed August 8, 2003, it was surprisingly and unexpectedly discovered that the brominated polystyrene resin binds anthocyanins less tightly than non-brominated polystyrene resins, but still allowed for the separation of anthocyanins from undesired extraneous impurities that are more polar than the anthocyanins (see paragraph [0036]).

In light of the foregoing remarks, it is asserted that claims 1-9, 11, and 14-28 as presently pending are patentable over the cited references. Withdrawal of this rejection is respectfully requested.

2. Claims 61-62 and 70 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Levy et al. in view of S.O.R.I. The Examiner states that Levy discloses a dry aqueous-alcoholic blueberry extract which contains anthocyanosides in an amount corresponding to 15% of anthocyanidins, but states Levy differs from the present invention in that that Levy does not use a brominated polystyrene resin. The Examiner then states that S.O.R.I. discloses

a process for extracting anthocyanins from certain fruits and berries to provide an unpurified extract containing 27 to 30% anthocyanins. This rejection is respectfully traversed.

It is maintained that Levy does not provide an enabling disclosure for a purified blueberry extract and consequently claims 61-62 and 70 are not obvious in view of Levy. It is well established that in order for a reference to anticipate or obviate a compound, the reference must contain an enabling disclosure. *In re LeGrice*, 301 F.2d 929, 133 USPQ 365 (CCPA 1962), and the courts have ruled that "if the prior art of record **fails to disclose or render obvious a method for making a claimed compound**, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public" (emphasis added). *In re Hoeksema*, 399 F.2d 269, 158 USPQ 597 (CCPA 1968). Thus, while Example 17 of Levy states that a blueberry extract was utilized, the material used by Levy was in fact a bilberry extract based on the evidence and arguments presented in the Amendment filed August 8, 2003, which are reiterated in part below for the Examiner's convenience. It is noted that in his final Office Action the Examiner did not indicate why he did not find the previously submitted evidence and arguments persuasive, and it is respectfully requested that the Examiner reconsider the supporting documentation filed August 8, 2003.

As stated in the Amendment filed August 8, 2003, the fact that extract used by Levy was actually a bilberry extract rather than a blueberry extract can be demonstrated as follows. Levy states that the extract was purchased from Indena. Enclosed with the response filed August 8, 2003 was a print out of standardized extracts supplied by Indena (available on the World Wide Web at the following URL: www.indena.com). A review of this list will show that the only berry extract sold by Indena is a bilberry (i.e., *Vaccinium myrtillus*) extract. Although bilberry (also known as "European blueberry") is sometimes simply called "blueberry" in some European languages (see printout obtained on the World Wide Web at the following URL: www.botanicalpathways.com), bilberry and blueberry are in fact two distinct species (see printouts obtained on the World Wide Web at the following URL: www.hollandandbarrett.com).

Further submitted herewith is a product specification sheet from FutureCeuticals, the supplier of the blueberry starting material used in Example 4 of the present invention. This specification sheet states that the FutureCeuticals' wild blueberry product is an extract of the species *Vaccinium angustifolium*, which is clearly different than the *Vaccinium myrtillus* extract used by Levy. As stated in the Amendment filed August 8, 2003, each anthocyanin-containing compound has a unique profile, i.e., the occurrence and percentages of

anthocyanins in plants, fruits, etc. is different for each species. Accordingly, raw materials such as bilberry and blueberry contain different types and concentrations of anthocyanins, and therefore purified extracts obtained from bilberry and blueberry extracts will likewise contain different types and concentrations of the anthocyanins see Chapter 3 from "The Flavonoids: Advances in Research" (J.B. Harborne and T.J. Mabry; Chapman and Hall, 1982) submitted with the Amendment filed August 8, 2003).

Based on the above information, it is asserted that the extract used in Levy's Example 17 was a bilberry extract, not a blueberry extract. Accordingly, claims 61-62 and 70, which are drawn to blueberry extracts, are not obvious in view of Levy. On this basis alone, the Section 103(a) rejection over Levy should be withdrawn.

It is further asserted that the combination of Levy with the S.O.R.I. reference does not render the compositions of claims 61-62 and 70 obvious. The Examiner asserts that S.O.R.I. discloses a process for extracting anthocyanins from certain fruits and berries to provide an unpurified extract containing 27 to 30% anthocyanins at page 2, lines 55-68. However, the Examiner will note that lines 55-58 describe a black currant extract (see page 2, line 53 of S.O.R.I.), whereas claims 61-62 and 70 recite a blueberry extract. Accordingly, there is nothing in the S.O.R.I. reference that could be combined with the Levy reference to provide the compositions of claims 61-62 and 70.

Finally, the Examiner asserts on page 6 of the final Office Action that "both references have commonly shared the process of preparing the certain concentration range of anthocyanosides" and that "Levy et al. does disclose the formation of dry aqueous-alcoholic blueberry extract which contains anthocyanosides in an amount corresponding to 15% of anthocyanidins." However, it is maintained that Levy does not disclose any method of isolating anthocyanidins from plant matter, let alone a method of preparing a blueberry extract enriched in anthocyanidins. Rather, Levy discloses a method of preparing a composition that incorporates polyphenols, and the Examiner will note that each example in Levy purchased a commercially available polyphenol. In any event, claims 61-62 and 70 are composition claims, and consequently any method disclosed by Levy is immaterial to the patentability of these claims. Thus, the Examiner's conclusion on page 6 of the Office Action that it would have been obvious to incorporate the teachings of S.O.R.I.'s anionic resins into the Levy process to enhance the purification process is irrelevant.

For the reasons presented above, it is believed that claims 61-62 and 70 as presently amended are clearly distinguished over the cited references, and withdrawal of the Section 103(a) rejection over Levy in view of S.O.R.I. is respectfully requested.

3. Claims 65-66, 69, and 71-72 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Gabetta et al. in view of Langston (U.S. Patent No. 4,500,556) and S.O.R.I. It is noted that the Examiner clarified the status of claim 69 in the Interview Summary, stating that claim 69 was inadvertently omitted in the rejection based on Gabetta et al. The Examiner states that Gabetta discloses a commercial *Vaccinium myrtillus* extract containing 35% of anthocyanosides, but that Gabetta differs from the present invention in that Gabetta does not disclose the use of a brominated polystyrene resin or a purified bilberry extract comprising 8-12% anthocyanins. The Examiner further states that S.O.R.I. discloses a process for extracting anthocyanins which utilizes anion exchange resin. This rejection is respectfully traversed.

It is maintained that Gabetta does not provide an enabling disclosure for a purified blueberry extract and consequently claims 65-66, 69, and 71-72 are not obvious in view of Gabetta, alone or in combination with the other cited references.

Independent claim 65 was previously amended in the paper filed August 8, 2003 to recite a purified bilberry extract prepared according to the method of claim 1, wherein the enriched composition has an HPLC chromatogram as shown in Figure 3 or Figure 4. Claim 66 depends from claim 65 and thus includes the novel elements of claim 65. In addition it was argued in the Amendment filed August 8, 2003, that not only does Gabetta fail to provide HPLC chromatograms of his isolated compounds, but since Gabetta does not teach or even suggest using a brominated polystyrene resin to purify his extract, Gabetta could not provide a compositions of claims 65 and 66 having an HPLC chromatogram as shown in Figure 3 or Figure 4. The recited HPLC chromatograms are unique, identifying "fingerprints" which clearly distinguish the composition of claim 61 over the Gabetta reference. However, the Examiner did not comment on this limitation, let alone state why he did not believe that this amendment does not distinguish the compositions of claims 65 and 66 over the Gabetta composition.

While it is believed that the claims pending upon entry of the August 8, 2003 amendment were clearly distinguished over Gabetta, claims 65, 69 and 71-72 have been further amended herein to include the limitation that during the process of preparing the extract, no bisulfite ions were added. Support for this amendment can be found at paragraphs [0041] - [0050]. Specifically, paragraph [0041] states that the one-column process of this invention "eliminates the sulfitation step . . . of the two column purification method of this invention, thus advantageously eliminating the need to use a sulfiting reagent." In contrast,

the Gabetta method of isolating anthocyanins requires the addition of an excess of bisulfite ions during the extraction and isolation process, which form adducts with the anthocyanins (column 1, lines 56-59). Accordingly, since the Gabetta compositions most likely include residual bisulfite ions resulting from the addition of bisulfite during the preparation of the extract, the compositions of claims 65-66, 69, and 71-72 are not obvious in view of Gabetta.

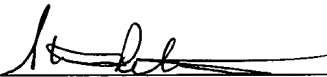
Furthermore, the reasons provided on pages 8-10 of the final Office Action for rejecting claims 65-66, 69, and 71-72 address what the Examiner believes to be similarities between the method of the present invention and the methods of the cited references. Given that claims 65-66, 69, and 71-72 are composition claims, the Examiner's comments on pages 8-10 of the Office Action are irrelevant to the patentability of claims 65-66, 69 and 71-72.

CONCLUSIONS

All outstanding rejections having been addressed, claims 1-9, 11, 14-28, 61-62, 65-66, and 69-72 are believed to be in condition for allowance, and such action is respectfully requested. No fee is believed due as a result of this Amendment. However, should any fees be due the Examiner is authorized to charge Deposit Account No. 50-1123. If any questions or issues remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

2/4/04
Dated


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